

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:)

Wray, Ziegler, and Brock)

**NASHVILLE HEALTHCARE DEFENDANTS’
MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO STRIKE MATTHEW C. LEE, M.D., R.Ph., M.S.
AS CASE-SPECIFIC EXPERT**

Saint Thomas Outpatient Neurosurgical Center, LLC (“STOPNC”); Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Saint Thomas Health; Saint Thomas Network; and Saint Thomas West Hospital f/k/a St. Thomas Hospital (“Nashville Healthcare Defendants”) move this Court, pursuant to Federal Rules of Civil Procedure 16, 26, and 37, to strike Matthew C. Lee, M.D., R.Ph., M.S. as a case-specific expert in the *Wray, Ziegler, and Brock* cases.

On March 7, 2016, counsel for the *Wray, Ziegler, and Brock* plaintiffs served Dr. Lee’s “case-specific” expert reports. However, even under the most generous application of the scheduling orders in this case, Dr. Lee is a common issue expert. As a common issue expert, the plaintiffs were required to disclose Dr. Lee by December 16, 2015.¹ Instead, the plaintiffs disclosed Dr. Lee nearly **three months** after the

¹ Dkt. 2330.

deadline for common issue expert reports, in an apparent attempt to take advantage of the phasing of this case. The plaintiffs' failure to comply with the Court's scheduling order warrants striking Dr. Lee as a case-specific expert.

LEGAL AUTHORITY

Fed. R. Civ. P. 16(b) authorizes the Court to set a timetable for expert disclosures.² The Court's timetable for expert disclosures "promotes fairness both in the discovery process and at trial."³ Fed. R. Civ. P. 26(a)(2)(D) provides that "a party must make [expert] disclosures at the times and in the sequence that the court orders."⁴ If a party fails to disclose an expert witness as required by Fed. R. Civ. P. 26(a), "the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or harmless."⁵

PROCEDURAL HISTORY

As this Court is well aware, it has adopted a phased approach to this litigation, phasing discovery into "common issue" discovery, followed by "case-specific" discovery. This includes the phasing of expert discovery, first common issue and then case-specific.

The Court's September 18, 2014 Order Regarding Common Issue Discovery defines a "common issue" as "an issue that pertains to *all or a substantial number of* cases in the Multidistrict Litigation ("MDL")."⁶ The same Order defines a "case specific

² Fed. R. Civ. P. 16(b).

³ *Macaulay v. Anas*, 321 F.3d 45, 50 (1st Cir. 2003).

⁴ Fed. R. Civ. P. 26(a)(2)(D).

⁵ Fed. R. Civ. P. 37(c).

⁶ Dkt. 1425 at n. 1 (emphasis added).

issue” as “an issue that pertains to a single case or a small number of cases.”⁷ Notably, these definitions were proposed by the PSC,⁸ and ultimately adopted by the Court.

The Court’s October 14, 2015 Order set the deadline for the Plaintiffs’ common issue expert reports as December 16, 2015.⁹ The Court’s January 20, 2016 Order set the deadline for the Plaintiffs’ case-specific expert reports as March 7, 2016.¹⁰

On March 7, 2016, counsel for the *Wray*, *Ziegler*, and *Brock* plaintiffs served Dr. Lee’s “case-specific” expert reports on the Nashville Healthcare Defendants. However, they are in no way case-specific reports, but are instead just more common issue purchaser expert reports. If the Plaintiffs wished to disclose Dr. Lee, they were free to – and were required to – disclose him in December. The Plaintiffs should not be able to take advantage of the Court’s phasing of this MDL by withholding common issue experts until the case-specific phase.

PLAINTIFFS’ FAILURE TO COMPLY WITH SCHEDULING ORDER

Dr. Lee’s “case-specific” reports do *not* offer opinions on case-specific issues. In fact, virtually all of Dr. Lee’s opinions are identical to the opinions disclosed by the PSC’s common issue experts. Dr. Lee’s “case-specific” reports are attached to this memorandum of law for the Court’s review.¹¹ Dr. Lee is not a case-specific issue expert under the definition of the Court’s orders. The Plaintiffs failed to comply with the Court’s scheduling order by disclosing Dr. Lee as a common issue expert under the guise of a

⁷ *Id.*

⁸ Dkt. 837.

⁹ Dkt. 2330.

¹⁰ Dkt. 2596.

¹¹ *Brock* Report attached as Exhibit 1; *Ziegler* Report attached as Exhibit 2; *Wray* Report attached as Exhibit 3.

“case-specific” expert, nearly **three months** after the deadline to disclose common issue experts. Examples of that failure are outlined below.

The PSC disclosed common issue experts on December 16, 2015. Their common issue expert opinions include:

1. Products from compounding pharmacies are inherently less safe and more risky than FDA approved drugs made by licensed pharmaceutical manufacturers.¹²
2. It was a breach below the applicable standard of care for Saint Thomas Neurosurgical to purchase steroids in bulk from a compounding pharmacy.¹³
3. During all relevant times, there were manufactured and FDA-approved steroids commercially available for use in ESIs.¹⁴
4. It was a breach below the applicable standard of care for Saint Thomas Neurosurgical to purchase steroids from a compounding pharmacy.¹⁵
5. It was a breach below the applicable standard of care to purchase steroids from a compounding pharmacy without patient specific prescriptions.¹⁶
6. Untrained employees, without any knowledge of pharmaceutical rules and processes, should not be permitted to make [purchasing] decisions on their own.¹⁷
7. Saint Thomas Neurosurgical knew or should have known that medications purchased from NECC could only be acquired and dispensed pursuant to individual patient-specific prescriptions.¹⁸
8. Saint Thomas Neurosurgical was negligent, reckless and fell below the standard of care by not knowing or learning about the rules applicable to pharmacy purchases.¹⁹
9. Saint Thomas Neurosurgical, its agents and employees were negligent, reckless and fell below the standard of care when it ignored certain red flags regarding NECC’s practices.²⁰

¹² Rule 26 Disclosure of James Gray, Pharm.D., MBA, Attached as Exhibit 4.

¹³ Rule 26 Disclosure of Lawrence Winikur, MD, Attached as Exhibit 5.

¹⁴ Rule 26 Disclosure of John Stephenson, MD, Attached as Exhibit 6.

¹⁵ Exhibit 4.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

10. Saint Thomas Health, Saint Thomas Network, Saint Thomas Hospital, and Saint Thomas Neurosurgical, all as part of the Saint Thomas Health system, failed to take appropriate steps to insure that appropriately trained personnel were in place at Saint Thomas Neurosurgical to protect the safety of patients with regard to the procurement of steroids for use in ESIs.²¹
11. The above described conduct resulted in or caused injuries that otherwise would not have occurred.²²

Dr. Lee's "case-specific" opinions for *Brock*, *Ziegler*, and *Wray* include:

1. Purchasing drugs from a compounding pharmacy are significantly more dangerous than purchasing drugs from an FDA approved manufacturer.
2. St. Thomas Outpatient Neurosurgical Center failed [*sic*] below the standard of care in purchasing form NECC by bulk rather than by individual prescriptions, compounded drugs manufactured by NECC.
3. There were commercially available steroids for use in epidural spinal injections.
4. It was below the standard of care for St. Thomas Outpatient Neurosurgical Center to purchase steroids from a compounding pharmacy.
5. It was further below the standard of care to purchase said drugs without a patient specific prescription.
6. The employees and officers of St. Thomas Outpatient Neurosurgery Center were untrained in the buying of these drugs and should not have been permitted to make the decision to buy compounding drugs from NECC.
7. The Defendants and all of them involved in the buying of compounded drugs knew or should have known that medications purchased from NECC could only be acquired and dispensed pursuant to an individual patient specific prescription.
8. The Defendants and all of them involved were negligent and fell below the standard of care by not knowing or learning the rules applicable to pharmacy purchasing.

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

9. The actions of NECC should have raised a red flag regarding NECC's practices of producing compounded drugs and were negligent and reckless in ignoring these red flags.
10. The St. Thomas Health System failed in its organization and regulation to educate and inform St. Thomas Outpatient Neurosurgical Center that they could not buy in bulk drugs from NECC and further, they fail [*sic*] below the standard of care in ensuring that appropriately trained personnel were performing the job at St. Thomas Outpatient Neurosurgical Center of purchasing drugs pursuant to the appropriate standards of medical practice.
11. It is my opinion that [the Defendants] failed to act with ordinary and reasonable care in accordance with the standard of care in Nashville, Tennessee, in the purchase of bulk, non-patient-specific, high-risk sterile injectable medications from the New England Compounding Pharmacy in June, July, and August of 2012.

The *only* "case-specific" opinions offered by Dr. Lee that *mention* the plaintiffs include:

1. It is my opinion that the above described conduct resulted in injury and death and would not have occurred and particularly injured Ms. Brock by causing her to contract meningitis.
2. Further, it is my opinion that the negligence of [the Defendants] caused Denis Brock to suffer injuries, including fungal meningitis and the symptoms, pain and suffering from this fungal meningitis medicine used to treat this fungal meningitis, which she would not otherwise have suffered.
3. It is my opinion that the negligence of [the Defendants] caused Adam Ziegler to suffer injuries that he would not otherwise have suffered.
4. It is my opinion that the negligence of [the Defendants] caused Jane Wray to suffer injuries that she would not have otherwise suffered.

The Plaintiffs do not even make a decent effort to characterize Dr. Lee's report as a case-specific report. Dr. Lee cannot simply add a plaintiff's name to a common issue opinion to qualify the opinion as case-specific.

Dr. Lee's "case-specific" opinions are identical to the PSC's common issue expert opinions. The PSC was required to disclose Dr. Lee by December 16, 2015. Dr.

Lee should be stricken as a case-specific expert, and the Plaintiffs should not be allowed to use his opinions moving forward.

CONCLUSION

Disclosing Dr. Lee as a case-specific expert is a blatant attempt by the PSC to exploit the Court's decision to phase the discovery process. Dr. Lee's "case-specific" opinions for the *Wray*, *Ziegler*, and *Brock* plaintiffs are identical to the PSC's common issue expert opinions. Disclosing Dr. Lee nearly **three months** after the Court's deadline for common expert reports is a violation of the Court's scheduling order. The Nashville Healthcare Defendants respectfully request the Court strike Dr. Lee and not allow the *Wray*, *Ziegler*, and *Brock* plaintiffs to use Dr. Lee's opinions moving forward.

LOCAL RULE 7.1

Pursuant to LR 7.1, the Defendants have made a good-faith effort to resolve this dispute, without success. On March 20, 2016, counsel for the Defendants emailed counsel for the Plaintiffs asking them to strike Dr. Lee as a case-specific expert.²³ Counsel for the Plaintiffs requested the Defendants' reasoning for the request. Counsel for the Defendants explained that Dr. Lee's case-specific reports contain common issue opinions, which required him to be disclosed as a common issue expert. Counsel for the Plaintiffs responded, "It sounds like your firm is operating from a misunderstanding of MDL practice." On March 28, 2016, counsel for the Plaintiffs refused to strike Dr. Lee.

²³ Correspondence attached as Exhibit 7.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

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* Admitted pursuant to MDL Order No. 1.

** Admitted *pro hac vice*.

**SAINT THOMAS WEST HOSPITAL,
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NETWORK, AND SAINT THOMAS HEALTH**

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 29th day of March, 2016.

/s/ Chris J. Tardio